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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/657,722	09/08/2000	Pramod K. Srivastava	8449-115-999	8697	
20583	7590 05/03/2002			==	
PENNIE AND EDMONDS			EXAMINER		
	55 AVENUE OF THE AMERICAS W YORK, NY 100362711		BANSAL, GEETHA P		
			ART UNIT	PAPER NUMBER	
			1642	7	
			DATE MAILED: 05/03/2002	1	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No	· philodin(s)	0	
Office Action Summary	Examiner	7,722 Srua		
	Geetto	$\Omega_{\alpha}$	Group Art Unit	
—The MAILING DATE of this			1642	<u> </u>
-The MAILING DATE of this communication appears	s on the cover	sheet beneath the co	orrespondence a	ddress
PridfrR ply	•			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO OF THIS COMMUNICATION.	EXPIRE	3month(s)	FROM THE MAI	LING DATE
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.1 from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a replectified in NO period for reply is specified above, such period shall, by default, experience to reply within the set or extended period for reply will, by statute</li> </ul>	ly within the statuto	ery minimum of thirty (30)	days will be considere	ed timely.
Status	• .			
Responsive to communication(s) filed on 1/14/02				
☐ This action is FINAL.		-		•
Since this application is in condition for allowance except for accordance with the practice under Ex parte Quayle, 1935	or formal matters C.D. 1 1; 453 O	s, prosecution as to t .G. 213.	the merits is clos	ed in
Disp sition of Claims				
@\Claim(s) _19-51				
<ul> <li>Claim(s) 19-51</li> <li>Of the above claim(s) 29, 21, 32-51</li> <li>□ Claim(s)</li> </ul>	<del></del>	is/are pe	ending in the appli	cation.
Claim(c)	<del></del>	is/are w	ithdrawn from con	sideration.
© Claim(s) 19,22 - 3	<del></del>	is/are re	jected.	
		is/are ob	ected to	
☐ Claim(s)		are subj	ect to restriction o	r election
Application Papers		requiren	nent.	
☐ See the attached Notice of Draftsperson's Patent Drawing R	Review PTO-948			
☐ The proposed drawing correction, filed on	is □appro	ved		
☐ The drawing(s) filed on is/are objected	to by the Exam	iner.		
☐ The specification is objected to by the Examiner.	,			
☐ The oath or declaration is objected to by the Examiner.				
Pri rity under 35 U.S.C. § 119 (a)-(d)	,			
<ul> <li>□ Acknowledgment is made of a claim for foreign priority under</li> <li>□ All □ Some* □ None of the CERTIFIED copies of the</li> <li>□ received.</li> </ul>	r 35 U.S.C. § 11 priority docume	9(a)-(d). nts have been		
☐ received in Application No. (Series Code/Serial Number)_ ☐ received in this national stage application from the Interna	utional Bureau (F	PCT Rule 1 7 2/a))	·	
*Certified copies not received:	,	· · · · · · · · · · · · · · · · · · ·		
Attachment(s)			•	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)☐ Notice of Reference(s) Cited, PTO-892				
	•	☐ Notice of Informal		
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948		☐ Other		
Office Act	ti n Summary			
J. S. Patent and Trademark Office  **TO-326 (Rev. 9-97)  **U.S. GPO: 19	997-433-221/62717			

Part of Paper No.\_\_\_

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## **DETAILED ACTION**

1. Applicant's election with traverse of Group II in Paper No. 6/C is acknowledged. The traversal is on the ground(s) that Group II invention can be searched together with the Group III invention, and that it would not be serious burden as the Groups have also been classified in the same Group. However, this is not found persuasive because the two groups are not drawn to the same-subject matter upon reviewing the claims. Group II invention is drawn to a composition comprising a population of peptides, whereas the Group III invention is drawn to a single peptide. These two Groups are distinct and independent of each other.

The requirement is still deemed proper and is therefore made FINAL. Claims 19, 22-31 are being examined.

## Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 19, 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A. Claim 19 is indefinite in that it is not clear if the population of stress protein peptide complexes are non-covalently associated with each other, or that each of the stress protein is non-covalently associated with a peptide
- B. Claim 19 is unclear in that the claim preamble does not relate to the conclusion.
- C. Claim 19 is indefinite in that it is not clear what the metes and bound of "amount" is.
- D. It is not clear in claim 24 what the metes and bounds are of "low pH".
- E. Claims 28-29 are ambiguous in the recitation of "cells have been proliferated in vitro" or "cells have been proliferated in vivo".

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 22-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for heat shock proteins 70, 90, gp96, does not reasonably provide enablement for stress-proteins in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. The specification contemplates/ teaches the making and using of heat shock protein 70, 90, gp96 associated with peptides, and the fact that stress proteins includes a vast number of proteins that are induced in response to a range of different stresses including heat shock, nutrient deprivation, oxygen radicals, metabolic disruption, viral infection (see Young, 1990; reference EE on the IDS). Furthermore, it appears that not all hsps are equivalent in their ability to exert their antigen presenting properties (see Srivastava, 1993 at least at page 166, section H- last 6-7 lines; reference DK in the IDS). Therefore, it is not predictable if all stress protein are associated with peptides, and secondly whether a population of peptides can be obtained from them by the same methods. One of skill in the art would not be able to practice the claimed invention without undue burden, as one of skill in the art is not given sufficient in the specification as to all the stress proteins that are available in the general scheme of biological systems and the stresses that are imposed upon them, leading to their induction.

- 5. No claims are allowed.
- 6. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays, and alternate Wednesdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308-3995.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 5, 2002.

GEETHA P. BANSAL